#### Idaho National Engineering and Environmental Laboratory

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Program Requirements	6.1 DOCUMENT CONTROL	Identifier:	PRD-5077
Document		Revision:	3
Companywide		Page:	<b>1</b> of 6
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Manual: 13A—Quality and Requirements

Management Program Documents

## 1. PURPOSE

This Program Requirements Document (PRD) identifies requirements and responsibilities to ensure that specified *documents* (see def.), either in hard copy or electronic media, including latest changes thereto, are reviewed for adequacy, approved for release, and distributed to and used at the location where the work is being performed. See Appendix A for requirements basis.

#### 2. APPLICABILITY

This PRD applies to company organizations involved in development, review, *approval* (see def.), revision, distribution, or use of *controlled documents* (see def.).

#### 3. RESPONSIBILITIES

## 3.1 Support Services Organization

The support services organization is responsible for establishing and implementing the *document control* (see def.) program.

## 3.2 Document and Records Management Organization

The document and records management organization is responsible for managing controlled documents in accordance with the requirements of this PRD.

#### 3.3 Company Personnel

Personnel who prepare, process, or use controlled documents for *activities affecting quality* (see def.) are responsible for complying with implementing documents of the document control program.

			(11,00,2001 100,00)
Program Requirements	6.1 DOCUMENT CONTROL	Identifier:	PRD-5077
Document		Revision:	3
Companywide		Page:	<b>2</b> of 6

## 4. **REQUIREMENTS**

## 4.1 Companywide Applications

The requirements identified in this subsection (4.1) apply to the entire company unless exempted by INT-17, QA PRD Introduction, Subsection 2.

#### **4.1.1** Basic

- 4.1.1.1 The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, *procedures* (see def.), and drawings shall be controlled to ensure that correct documents are being employed. [NQA-1-1997, Requirement 6, 100 1s; DOE/RW-0333P 6.2.1]
- 4.1.1.2 Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel including the document owner. [NQA-1-1997, Requirement 6, 100 2s; DOE/RW-0333P 6.2.6.B]
- 4.1.1.3 The organization and individuals responsible for the preparation, review, document approval, approval for release, distribution, and maintenance of controlled documents shall be identified. [NQA-1-1997, Requirement 6, 200 (c); DOE/RW-0333P 6.2.2 and 6.2.4]

#### 4.1.2 Distribution and Use of Documents

- 4.1.2.1 The distribution and use of documents, including changes and editorial corrections to documents, shall include the following controls [NQA-1-1997, Requirement 6, 200; DOE/RW-0333P 6.2.5]:
  - A. The documents to be controlled shall be identified. [NQA-1-1997, Requirement 6, 200(a)]
  - B. Controlled documents will be reviewed for completeness, and approved prior to distribution. [NQA-1-1997, Requirement 6, 200(d)]
  - C. A method shall be established to ensure the correct controlled documents, either in hardcopy or electronic media, are distributed to, or made available to, and used at, the work location. [NQA-1-1997, Requirement 6, 200(b); DOE/RW-0333P 6.2.5.A]
  - D. Effective dates shall be established for approved implementing documents. [NQA-1-1997, Requirement 6, 200(e); DOE/RW-0333P 6.2.5.B]

			(11/03/2001 100)
Program Requirements	6.1 DOCUMENT CONTROL	Identifier:	PRD-5077
Document		Revision:	3
Companywide		Page:	<b>3</b> of 6

- E. A method shall be established to ensure the disposition of obsolete or superseded documents so they are controlled and not used to perform work. [NQA-1-1997, Requirement 6, 200(e); DOE/RW-0333P 6.2.5.C]
- F. A method shall be established to identify the current status of each document that is required to be controlled (i.e., being revised, obsolete). [NQA-1-1997, Requirement 6, 200(e); DOE/RW-0333P 6.2.5.D]

### 4.1.3 Major Document Changes

- 4.1.3.1 Changes to documents, except *minor changes* (see def.), shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. [NQA-1-1997, Requirement 6, 301 1s]
- 4.1.3.2 The individual reviewing controlled document changes shall have access to pertinent document background data or information upon which to base their changes and approval. [NQA-1-1997, Requirement 6, 301 2s]

## 4.1.4 Minor Document Changes

- 4.1.4.1 Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents. However, such corrections shall be distributed as a revision or change to the document. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the person(s) who can authorize such a decision shall be clearly delineated. [NQA-1-1997, Requirement 6, 302]
- 4.1.4.2 Editorial and minor corrections may be made to documents without being subject to review requirements, but such corrections shall be distributed as a revision or change to the document. The following are considered editorial changes [DOE/RW-0333P 6.2.8 and 6.2.8.A]:
  - A. Correcting grammar or spelling. [DOE/RW-0333P 6.2.8.A.1]
  - B. Renumbering sections or attachments that do not affect the chronological sequence of work. [DOE/RW-0333P 6.2.8.A.2]
  - C. Changing the title or number of the document. [DOE/RW-0333P 6.2.8.A.3]

			(11/05/2001 1007.00)
Program Requirements	6.1 DOCUMENT CONTROL	Identifier:	PRD-5077
Document		Revision:	3
Companywide		Page:	<b>4</b> of 6

D. Updating organizational titles. [DOE/RW-0333P 6.2.8.A.4]

**NOTE:** A change in an organizational title accompanied by a change in responsibilities is <u>not</u> considered an editorial correction. [DOE/RW-0333P 6.2.8.A.4 Note]

#### 4.1.5 Incorporating Changes

- 4.1.5.1 Implementing documents shall define the method used to incorporate changes. [DOE/RW-0333P 6.2.6.C.1s]
- 4.1.5.2 Implementing documents shall require that a history of changes to Quality Assurance Program documents, including the reasons for the changes, be documented and maintained. This document history shall be reviewed each time additional changes to the document are proposed. [DOE/RW-0333P 6.2.6.D]

## **4.1.6** Expedited Document Changes

- 4.1.6.1 If an activity cannot be performed as listed in a document, and the change process would cause unreasonable delays, then an expedited change may be made at the work location by responsible management. [DOE/RW-0333P 6.2.7]
- After the *expedited change* (see def.) has been authorized, the changes shall be processed through the normal change process. This processing shall occur in a timely manner consistent with the type and nature of the document being changed. [DOE/RW-0333P 6.2.7.A]
- 4.1.6.3 Implementing documents shall describe the process to control expedited changes according to the following requirements [DOE/RW-0333P 6.2.7.B]:
  - A. The level of management with the authority to make expedited changes shall be identified. [DOE/RW-0333P 6.2.7.B.1]
  - B. The time limits for processing expedited changes through the normal change process shall be specified. [DOE/RW-0333P 6.2.7.B.2]
  - C. An evaluation of the work shall be performed if the normal review process results in a change that is different from the expedited change. [DOE/RW-0333P 6.2.7.B.3]

			(11/03/2001 1007.00)
Program Requirements	6.1 DOCUMENT CONTROL	Identifier:	PRD-5077
Document		Revision:	3
Companywide		Page:	<b>5</b> of 6

#### 4.1.7 Records

4.1.7.1 All records designated in implementing documents as *quality* assurance records (see def.) shall be controlled in accordance with PRD-5088, 17.1 Quality Assurance Records. [Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements]

# **4.2** Specific Requirements for DOE/RW-0333P QARD Revision 10 Applications

This subsection (4.2) contains additional requirements from the QARD (DOE/RW-0333P, Revision 10) which are specific to the Spent Nuclear Fuel Program.

## **4.2.1 Document Change Control**

- 4.2.1.1 Controlled documents, including changes to the documents, shall be reviewed in accordance the requirements of this PRD and DOE/RW-0333P, Subsection 2.2.10, Document Review, prior to approval for release. [DOE/RW-0333P 6.2.3 and 6.2.6.A]
- 4.2.1.2 If the defined method for incorporating change is other than reissue of the entire controlled document, the implementing document shall define the maximum number of changes permitted prior to requiring reissue of the entire controlled document.

  [DOE/RW-0333P 6.2.6.C.2s]
- 4.2.1.3 The organizational position responsible for approving the document for release shall approve editorial corrections.

  [DOE/RW-0333P 4.2.8.B]

#### 5. **DEFINITIONS**

Refer to LST-199, Definitions, in the QA PRD Manual for the definitions of the following terms:

activities affecting quality

approval

controlled document

document

document control

expedited change

			(11,00,2001 100)
Program Requirements	6.1 DOCUMENT CONTROL	Identifier:	PRD-5077
Document		Revision:	3
Companywide		Page:	<b>6</b> of 6

minor changes

procedure

quality assurance record

# 6. REFERENCES

ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications

DOE/RW-0333P, Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description, Revision 10

# 7. APPENDICES

Appendix A, 6.1 Basis

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Program Requirements	6.1 DOCUMENT CONTROL	Identifier:	PRD-5077
Document		Revision:	3
Companywide		Page:	<b>A1</b> of A2

# APPENDIX A

## 6.1 Basis

Source	Citation	Requirement	Comments
ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications, Requirement 6	100 1s	4.1.1.1	Consensus Requirement (CR)
NQA-1-1997, Requirement 6	100 2s	4.1.1.2	CR
NQA-1-1997, Requirement 6	200 (c)	4.1.1.3	CR
NQA-1-1997, Requirement 6	200	4.1.2.1	CR
NQA-1-1997, Requirement 6	200 (a)	4.1.2.1.A	CR
NQA-1-1997, Requirement 6	200 (b)	4.1.2.1.C	CR
NQA-1-1997, Requirement 6	200 (d)	4.1.2.1.B	CR
NQA-1-1997, Requirement 6	200 (e)	4.1.2.1.D	CR
NQA-1-1997, Requirement 6	200 (e)	4.1.2.1.E	CR
NQA-1-1997, Requirement 6	200 (e)	4.1.2.1.F	CR
NQA-1-1997, Requirement 6	301 1s	4.1.3.1	CR
NQA-1-1997, Requirement 6	301 2s	4.1.3.2	CR
NQA-1-1997, Requirement 6	302	4.1.4.1	CR
DOE/RW-0333P, Office of Civilian Radioactive Waste Management Program, Quality Assurance Requirements and Description, Revision 10	4.2.8.B	4.2.1.3	Specific Requirement (SR)
DOE/RW-0333P	6.2.1	4.1.1.1	CR
DOE/RW-0333P	6.2.2 and 6.2.4	4.1.1.3	CR
DOE/RW-0333P	6.2.3 and 6.2.6.A	4.2.1.1	SR
DOE/RW-0333P	6.2.5	4.1.2.1	CR
DOE/RW-0333P	6.2.5.A	4.1.2.1.C	CR
DOE/RW-0333P	6.2.5.B	4.1.2.1.D	CR
DOE/RW-0333P	6.2.5.C	4.1.2.1.E	CR
DOE/RW-0333P	6.2.5.D	4.1.2.1.F	CR
DOE/RW-0333P	6.2.6.B	4.1.1.2	CR
DOE/RW-0333P	6.2.6.D	4.1.5.2	CR
DOE/RW-0333P	6.2.6.C.1s	4.1.5.1	CR
DOE/RW-0333P	6.2.6.C.2s	4.2.1.2	SR
DOE/RW-0333P	6.2.7	4.1.6.1	CR
DOE/RW-0333P	6.2.7.A	4.1.6.2	CR
DOE/RW-0333P	6.2.7.B	4.1.6.3	CR
DOE/RW-0333P	6.2.7.B.1	4.1.6.3.A	CR
DOE/RW-0333P	6.2.7.B.2	4.1.6.3.B	CR
DOE/RW-0333P	6.2.7.B.3	4.1.6.3.C	CR

			(11/03/2001 - Kev. 00)	_
Program Requirements	6.1 DOCUMENT CONTROL	Identifier:	PRD-5077	]
Document		Revision:	3	
Companywide		Page:	<b>A2</b> of A2	

# APPENDIX A

## 6.1 Basis

Source	Citation	Requirement	Comments
DOE/RW-0333P	6.2.8 and 6.2.8.A	4.1.4.2	CR
DOE/RW-0333P	6.2.8.A.1	4.1.4.2.A	CR
DOE/RW-0333P	6.2.8.A.2	4.1.4.2.B	CR
DOE/RW-0333P	6.2.8.A.3	4.1.4.2.C	CR
DOE/RW-0333P	6.2.8.A.4	4.1.4.2.D	CR
DOE/RW-0333P	6.2.8.A.4	4.1.4.2 Note	CR
PRD-5088, 17.1 Quality Assurance Records	All	4.1.7.1	Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements